

Notice of Allowability

Application No.

10/030,390

Examiner

S. Devi, Ph.D.

Applicant(s)

HANS ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' amendment filed 05/09/06.
2. ☒ The allowed claim(s) ~~is/are~~ 10, 11, 31, 21-24, 26-28, 30 and 32, now renumbered as claims 1, 2, 3, 4-7, 8-10, 11 and 12 respectively.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

ATTACHMENT TO NOTICE OF ALLOWABILITY

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 05/09/06 in response to the non-final Office Action mailed 02/10/06.

Examiner's Amendment

- 2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Ms. Wendy Davis in a telephonic interview on 25 May 2006.

This application has been amended as indicated below. Claims 10, 31, 21, 22, 23, 27, 28 and 30 are amended as indicated below.

--Claim 10. (Currently amended). A method of treatment of a colon disorder ~~of in~~ in an individual[[,]] comprising ~~the~~ oral administration of a therapeutically effective amount of a recombinant food grade gram-positive ~~bacteria~~ bacterium expressing a trefoil ~~peptides~~ peptide in the colon of said individual.--

--Claim 31. (Currently amended). The method of claim 10, wherein the recombinant food grade gram-positive ~~bacteria are~~ bacterium is a lactic acid fermenting ~~bacteria~~ bacterium.--

--Claim 21. (Currently amended). The method of claim 31, wherein the lactic acid fermenting ~~bacteria are~~ bacterium is *Lactococcus* or *Lactobacillus* ~~bacteria~~.--

--Claim 22. (Currently amended). The method of claim 21, wherein the *Lactococcus* ~~bacteria are~~ is *Lactococcus lactis* ~~bacteria~~.--

--Claim 23. (Currently amended). The method of claim 10, wherein the trefoil ~~peptides are~~ peptide is TEF1 ~~peptides~~ peptide.--

--Claim 27. (Currently amended). The method of claim 10, wherein the recombinant food grade gram-positive ~~bacteria~~ bacterium ~~comprise~~ comprises a recombinant vector comprising ~~a trefoil peptide~~ coding sequence of said trefoil peptide under the control of a suitable promoter sequence and a suitable secretion signal sequence.--

--Claim 28. (Currently amended). The method of claim 10, wherein the recombinant food grade gram-positive ~~bacteria~~ bacterium ~~comprise~~ comprises [[a]] the nucleotide sequence of SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3.--

--Claim 30. (Currently amended). The method of claim 10, wherein the therapeutically effective amount of said recombinant food grade gram-positive bacterium is at least 10^8 ~~recombinant food grade gram-positive bacteria~~ cells of said bacterium.--

Status of Claims

- 3) Claims 10, 11, 21-23, 24, 27 and 28 have been amended via the amendment filed 05/09/06.
Claims 19, 20 and 29 have been canceled via the amendment filed 05/09/06.
New claims 30-32 have been added via the amendment filed 05/09/06.
Claims 10, 31, 21-23, 27, 28 and 30 have been amended via this Examiner's amendment.
Claims 10, 11, 21-24, 26-28 and 30-32 are pending and are under examination.

Objection(s) Withdrawn

- 4) The objection to the specification made in paragraph 6 of the Office Action mailed 02/10/06 is withdrawn in light of Applicants' amendment to the specification.

Rejection(s) Moot

- 5) The rejection of claims 19, 20 and 29 made in paragraph 16 of the Office Action mailed 02/10/06 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claims.
- 6) The rejection of claims 19, 20 and 29 made in paragraph 17 of the Office Action mailed 02/10/06 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is moot in light of Applicants' cancellation of the claims.
- 7) The rejection of claim 20 made in paragraph 17(b) of the Office Action mailed 02/10/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 8) The rejection of claims 19, 20 and 29 made in paragraph 17(c) of the Office Action mailed 02/10/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

- 9) The rejection of claim 10 and those dependent therefrom made in paragraph 16 of the Office Action mailed 02/10/06 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claim(s) and/or the base claim.

- 10)** The rejection of claims 10, 11 and 21-28 made in paragraph 17 of the Office Action mailed 02/10/06 under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn in light of Applicants' amendments to the claims and Applicants' arguments.
- 11)** The rejection of claim 10 made in paragraph 17(a) of the Office Action mailed 02/10/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment and Examiner's amendment to the claim.
- 12)** The rejection of claim 28 made in paragraph 17(c) of the Office Action mailed 02/10/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment and Examiner's amendment to the claim.
- 13)** The rejection of claims 11, 21-24 and 26-28 made in paragraph 17(c) of the Office Action mailed 02/10/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment and Examiner's amendment to the base claim.

Remarks

- 14)** Claims 10, 11, 31, 21-24, 26-28, 30 and 32, now renumbered as claims 1, 2, 3, 4-7, 8-10, 11 and 12 respectively, are allowed.
- 15)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted to the PTO Central Fax number (571) 273-8300 which receives transmissions 24 hours a day and 7 days a week.
- 16)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
- 17)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

May, 2006


S. DEVI, PH.D.
PRIMARY EXAMINER